



PATENT

Customer Number 22,852

Attorney Docket No. 5552.0265-04000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Heinz-Jürgen FRIESEN et al.

Application No.: 09/820,974

Filed: March 30, 2001

For: SHEET-LIKE DIAGNOSTIC
DEVICE

Group Art Unit: 1641

Examiner: Christopher L. CHIN

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TERMINAL DISCLAIMER

Sir:

Petitioner Dade Behring Marburg GmbH, duly organized under the laws of Germany, and having its principal place of business at Emil-von-Behring-Strasse 76, 35041 Marburg, Germany, represents that it is an assignee of the entire right, title, and interest to United States Patent Application No. 08/544,579, filed October 18, 1995, for Sheet-Like Diagnostic Device in the name of Heinz-Jürgen Friesen et al., now U.S. Reissue Patent No. RE37,437; and the entire right, title, and interest to United States Patent Application No. 09/820,974, filed March 30, 2001, also for Sheet-Like Diagnostic Device in the name of Heinz-Jürgen Friesen et al., by virtue of a name change from Behring Diagnostics GmbH to Dade Behring Marburg GmbH, which was recorded for parent United States Patent No. 4,861,711, granted August 29, 1989 ("the '711 patent"), at Reel 9197, Frame 0667. Behring Diagnostics GmbH was the sole assignee of the '711 patent by virtue of an assignment executed by Behringwerke Aktiengesellschaft.

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which was recorded at Reel 8842, Frame 0428. Behringwerke Aktiengesellschaft was the sole assignee of the '711 patent by virtue of an assignment executed by inventors Heinz-Jürgen Friesen, Gerd Grenner, Hans-Erwin Pauly, Helmut Kohl, Klaus Habenstein, and Joseph Stärk, which was recorded at Reel 4496, Frame 0646.

To obviate a double patenting rejection, Dade Behring Marburg GmbH hereby disclaims, under the provisions of 37 C.F.R. § 1.321, effective at the time that U.S. Patent Application No. 09/820,974 is granted, the terminal part of any patent granted on United States Patent Application No. 09/820,874, which would extend beyond the expiration date of United States Reissue Patent No. RE37,437, and hereby agrees that any patent so granted on United States Patent Application No. 09/820,974 shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to United States Reissue Patent No. RE37,437, this agreement to run with any patent granted on United States Patent Application No. 09/820,974 and to be binding upon the grantee, its successors or assigns.

In making the above disclaimer, the assignee does not disclaim the terminal part of any patent granted on United States Patent Application No. 09/820,974 that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. §§ 154 to 156 and 173 of United States Reissue Patent No. RE37,437, as presently shortened by any terminal disclaimer, in the event that United States Reissue Patent No. RE37,437 expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or in part, is terminally disclaimed under 37 C.F.R. § 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term, as presently shortened by any terminal disclaimer.

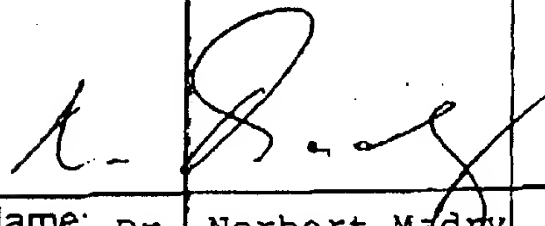
In accordance with the fee schedule set forth in 37 C.F.R. § 1.20(d), the required fee of \$110.00 is being filed with this disclaimer.

If there are any additional fees due in connection with the filing of this Terminal Disclaimer, please charge the fees to our Deposit Account No. 06-0916. If any further fee and/or petition is required for an extension of time under 37 C.F.R. § 1.136 and is not accounted for above, such an extension is requested and the fee should also be charged to Deposit Account No. 06-0916.


The undersigned is authorized to act on behalf of assignee, Dade Behring Marburg GmbH.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,


Name: Dr. Norbert Madry
Position: Managing Director

Dated: March 1, 2004


Name: Dr. Bernhard Auerbach
Position: Director Patents and Licenses

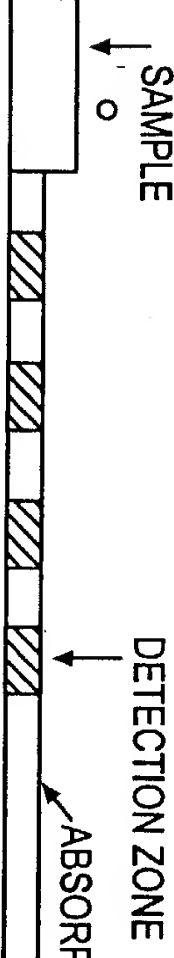
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EXAMPLES OF TEST ASSEMBLIES WITH SAMPLE OR WITH PREVIOUS DILUTION OF
SAMPLE IN THE FORM OF MOBILE PHASE

TEST PRINCIPLE							COMPLEX DETECTED
	I	II	III	IV	V	VI	
COMPETITIVE, FOR EXAMPLE:		○—"	∩ ₁		∩ ₂		"—○ ₁ —∩ ₂
		○—"			∩ ₁		"—○ ₁
		∩ ₁	○—"		∩ ₂		"—○ ₁ —∩ ₂
	Glc, TMB	○—"	∩ ₁ ^{GOD}		∩ ₂		"—○ ₁ —∩ ₂ "=POD
	Glc, TMB	○—"	∩ ₁	GOD OR GOD ₁	∩ ₂		"—○ ₁ —∩ ₂ "=POD
SANDWICH, FOR EXAMPLE:	TMB	○—"	∩ ₁	PERBORATE ₁	∩ ₂		"—○ ₁ —∩ ₂ "=POD
		∩ ₁	∩ ₂		∩ ₃		"—∩ ₁ —∩ ₂ —∩ ₃
IMMUNOMETRIC, FOR EXAMPLE:		∩ ₁			○		—○—"

FOR EXPLANATION OF SYMBOLS SEE SUMMARY FIG. 2

FIG. 1

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EXAMPLES OF TEST ASSEMBLIES HAVING A SEPARATE MOBILE PHASE

MOBILE PHASE SAMPLE DETECTION ZONE

↑ ↑ ↑
ABSORPTION ZONE

TEST PRINCIPLE	I	II	III	IV	V	VI
COMPETITIVE, FOR EXAMPLE: SANDWICH, FOR EXAMPLE: IMMUNOMETRIC, FOR EXAMPLE		○ ¹ —	○ ¹ ↓	Y ₁	Y ₂	"—○ ¹ Y ₂
INDIRECT DETECTION OF ANTIBODIES		Y ₁ "	○ ¹ ↓	Y ₂ "	Y ₃	"—○ ¹ Y ₂ Y ₃
ELA (ENZYME- LABELLED ANTIGEN)			Y ₁ ↓	○ ¹ —	Y ₂	"—○ ¹ Y ₂

GOD GLUCOSE OXIDASE; POD=PEROXIDASE; TMB=TETRAMETHYLBENZIDINE;
Glc OC-D-GLUCOSE
x¹ ↓ DELIVERY OF THE COMPONENT X TO THE PARTICULAR ZONE
○¹ COMPONENT ATTACHED TO SOLID PHASE
Y₁ ATTACHING COMPONENT (RECEPTOR)
Y₂ ANTIBODY OR RECEPTOR HAVING COMBINATION POINTS FOR ANOTHER RECEPTOR
" LABELLING; ○=COMPONENT WHICH CAN BE ATTACHED BY A RECEPTOR

FIG. 2